

REMARKS

This is a full and timely response to the outstanding nonfinal Office Action mailed November 15, 2005. Reconsideration and allowance of the application and presently pending claims, as amended, are respectfully requested.

Present Status of Patent Application

Upon entry of the amendments in this response, claims 1 and 3-20 are pending. In particular, Applicants have amended claims 1 and 2-5, have cancelled claim 2, and have added new claims 12-20. The prior art made of record has been considered, but is not believed to affect the patentability of the presently pending claims. Applicants believe that no new matter has been added and that a new search is not necessary.

Response to Objections to the Drawings

The Office Action objected to the drawings as failing to show every feature specified in the claims. Applicants respectfully traverse.

Specifically, the Office Action alleges that the drawings do not show the feature "each groove penetrat[ing] into the thickness of the body of the screw". Applicants respectfully disagree. First, Applicants presume that the Office Action is referring to the language of claim 7, which states "*the final portion of each groove* penetrates into the thickness of the body of the screw." (Emphasis added). Thus, for the subject matter of claim 7, it is the final portion, not the entirety of each groove, that penetrates the thickness of the body of the screw. Second, Applicants submit that FIGS. 1-3 of the present application can be viewed as illustrating the final portion of the groove 10 as penetrating into the thickness of the body of the screw. Additional drawings illustrating specific embodiments of the groove depth are not necessary for the understanding of the subject matter of claim 7.

Furthermore, the statutory requirements of the U.S. Patent Laws require only that a drawing (or drawings) is required only if necessary for an understanding of the subject matter sought to be patented. Frequently, the PTO issues patents that have no drawings at all, where the patented subject matter is understood based solely on the textual

description. In the present situation, additional drawings are not necessary for the understanding of the subject matter sought to be patented.

For this reason, the objections to the drawings should be withdrawn.

Response to Objection to the Claims

The Office Action objects to Claim 5 for informalities, alleging that "grooves varies" is incorrect usage. Claim 5 has been amended to obviate the rejection.

Claim Rejections Under 35 U.S.C. §112

The Office Action states that claim 5 is rejected as being indefinite; however, the text of the rejection refers to the language of claim 3. Thus, for the purposes of this response, Applicants have presumed rejection of claim 3 and have directed the following remarks to claim 3. Claim 3 has been amended to obviate the rejection.

Applicants wish to clarify that the foregoing amendments have been made for purposes of better defining the invention in response to the rejections made under 35 U.S.C. § 112, and not in response to rejections made based on prior art. Indeed, Applicants submit that no substantive limitations have been added to the claims. Therefore, no prosecution history estoppel arises from these amendments. *Black & Decker, Inc. v. Hoover Svc. Ctr.*, 886 F.2d 1285, 1294 n. 13 (Fed. Cir. 1989); *Andrew Corp. v. Gabriel Elects., Inc.*, 847 F.2d 819 (Fed. Cir. 1988); *Hi-Life Prods. Inc. v. Am. Nat'l. Water-Mattress Corp.*, 842 F.2d 323, 325 (Fed. Cir. 1988); *Mannesmann Demag Corp. v. Eng'd Metal Prods. Co., Inc.*, 793 F.2d 1279, 1284-1285 (Fed. Cir. 1986); *Moeller v. Ionetics, Inc.*, 794 F.2d 653 (Fed. Cir. 1986)

Claim Rejections Under 35 U.S.C. §103(a)

Claims 1-11 stand rejected under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 6,402,757 to Moore, III et al. in view of U.S. Patent No. 6,306,140 to Siddiqui.

Applicants respectfully traverse this rejection.

Amended claim 1 reads as follows:

An osteosynthesis and compression screw for coaptation of small bone fragments, the screw being formed by a single longitudinal body having a longitudinal axis, and comprising:

- a proximal portion formed by a screw head provided with an outside thread, said proximal portion being of diameter greater than the diameter of the remainder of the screw;
- an intermediate portion having no thread; and
- a distal portion provided with an outside thread;

wherein:

- *each of the screw head and the distal portion includes at least one helical groove*, firstly extending over the entire axial length of its thread, and secondly being formed through each thread in such a manner to form tapping means; and
- the terminal zone of the distal portion is provided with preparation means for preparing a housing in the bone fragments for receiving the intermediate and distal portions of the screw.

(Emphasis added). Applicants traverse the rejection and assertions in the Office Action and submit that the rejection of claim 1 under 35 U.S.C. §103 should be withdrawn because Moore et al. and Siddiqui, taken alone or in combination, do not disclose, teach, or suggest at least the highlighted portions in amended claim 1 above. In particular, neither Moore et al. nor Siddiqui disclose a helical groove. The grooves 23 and 32 of Moore et al. are generally straight or angled, but not helical. In fact, the Moore et al. reference discloses that the “cutting edges 32 are generally straight grooves formed in opposite sides of the threaded portion 48.” (Moore et al., Col. 3, lines 44-46). Siddiqui also fails to disclose, teach, or suggest a helical groove.

Applicants submit that a helical groove provides significant, unobvious advantages over that of the straight or angular grooves shown in the prior art as discussed on page 8, lines 9-14 of the Specification. For instance, while grooves such as those disclosed in the Moore et al. reference provide a cutting edge/tapping means, the grooves also introduce weak zones due to the removal of material from the screw body. However, the helical shape of the grooves of claim 1 distributes any possible weak zones around the longitudinal axis of the screw, thereby maintaining the overall strength of the screw, while retaining excellent and efficient tapping functions. The cited references fail to disclose, teach, or suggest a helical groove or the advantages conferred by such groove. Therefore, Applicants submit that claim 1 is not obvious over Moore et al. and/or Siddiqui, and the rejection of claim 1 should be withdrawn.

Applicants respectfully submit that pending dependent claims 3-12 include every feature of independent claim 1. Thus, pending dependent claims 3-12 are allowable over the prior art of record for at least the reasons set forth for claim 1, above. *In re Fine*, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988).

New Claims 12-20

Applicants respectfully submit that new claims 12-20 do not introduce new matter. Specifically, new claim 12 includes the deleted portions of amended claim 3, and support for new claims 13-20 can be found generally on pages 6 through 9 of the specification and/or in the original claims.

With respect to new claim 15, it reads in pertinent part, as follows:

An osteosynthesis and compression screw...wherein: each of the screw head and the distal portion includes at least one groove, firstly extending substantially over the entire axial length of its thread, and secondly being formed through each thread in such a manner to form tapping means, *wherein the depth of each groove varies regularly from the start towards the finish of each groove...*

(Emphasis added). Applicants respectfully submit that new claim 15 is allowable over the art of record because the art of record, taken alone or in combination, does not disclose, teach, or suggest at least the highlighted portions in new claim 15 above. In particular, the art of record does not disclose grooves having a depth that varies regularly from the start towards the finish of each groove.

Although the Office Action alleges that it would have been obvious to one of ordinary skill in the art to make the grooves 23 to have a variable depth (Office Action, page 5), Applicants respectfully submit that the above feature would not have been obvious to one of skill in the art. The advantages of varying the depth of the grooves are discussed on page 8, lines 3-8 and lines 21-29, and include increasing the general strength of the screw and reducing the loss of material relative to the longitudinal axis, thereby reducing the risk of weakening the screw. Neither grooves of variable depth nor the significant advantages provided by such grooves are taught or suggested by the cited references.

Furthermore, with respect to a variable depth groove, Applicants respectfully request support for the assertion of obviousness in the Office Action. Official notice unsupported by documentary evidence should only be taken by the Examiner where the facts asserted to be well-known, or to be common knowledge in the art, are capable of instant and unquestionable demonstration as being well-known. *In re Ahlert*, 424, F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970); see also MPEP § 2144.03. As noted by the court in *In re Ahlert* (Id.), the notice of facts beyond the record which may be taken by the Examiner must be "capable of such instant and unquestionable demonstration as to defy dispute" (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)).

Thus, Applicants respectfully submit that new claims 12-20 are allowable over the art of record and request allowance thereof.

CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicants respectfully submit that all objections and rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims 1 and 3-20 are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested. If, in the opinion of the Examiner, a telephone conference would expedite the examination of this matter, the Examiner is invited to call the undersigned agent at (770) 933-9500.

Respectfully submitted,



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